

CLAIMS

WHAT IS CLAIMED IS:

1. A medical article, comprising a coating disposed on at least a portion of an implantable medical device, the coating comprising:

5 (a) a fluorinated polymer; and

(b) a biologically beneficial polymer.

2. The medical article of Claim 1, wherein the implantable medical device is a stent.

3. The medical article of Claim 1, wherein the fluorinated polymer includes:

10 (a) products of polymerization of fluorinated olefins or mixtures thereof;

(b) products of polymerization of fluorinated cyclic esters;

(c) fluorine-containing cyclic polymers having a main chain with an asymmetrical cyclic structure; or

15 (d) copolymers of perfluoro-2,2-dimethyl-1,3-dioxole with perfluoroolefins or with perfluoro(alkyl vinyl) ethers.

4. The medical article of Claim 3, wherein the products of polymerization of fluorinated olefins are selected from a group consisting of poly(vinylidene fluoride-co-hexafluoropropene), poly(tetrafluoroethylene), fluorinated poly(ethylene-co-propylene), poly(hexafluoropropene), poly(chlorotrifluoroethylene), poly(vinylidene fluoride),
20 poly(vinylidene fluoride-co-tetrafluoroethylene), poly(tetrafluoroethylene-co-

hexafluoropropene), poly(tetrafluoroethylene-co-vinyl alcohol), poly(tetrafluoroethylene-co-vinyl acetate), poly(tetrafluoroethylene-co-propene), poly(hexafluoropropene-co-vinyl alcohol), poly(ethylene-co-tetrafluoroethylene), poly(ethylene-co-hexafluoropropene), and poly(vinylidene fluoride-co-chlorotrifluoroethylene).

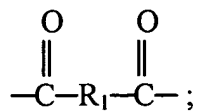
5 5. The medical article of Claim 3, wherein the products of polymerization of fluorinated cyclic esters is poly(perhalo-2,2-dimethyl-1,3-dioxole-co-perfluoro-2-methylene-methyl-1,3-dioxolane).

 6. The medical article of Claim 3, wherein the fluorine-containing cyclic polymers are selected from a group of polymers with repeating units of cyclically polymerized
10 perfluorallyl vinyl ether and/or perfluorobutenyl vinyl ether.

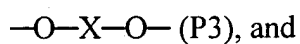
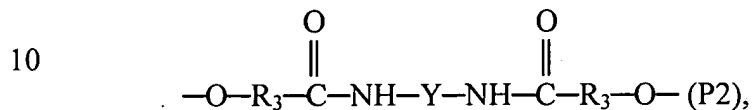
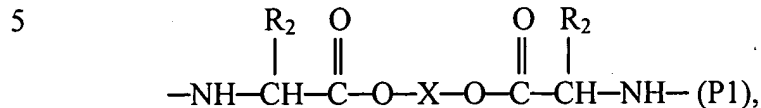
 7. The medical article of Claim 1, wherein the biologically beneficial polymer is selected from a group consisting of poly(ethylene-glycol), poly(ethylene-glycol)-block-poly(butylene-terephthalate)-block-poly(ethylene-glycol), poly(butylene-terephthalate)-block-poly(ethylene-glycol)-block poly(butylene-terephthalate), hyaluronic acid, derivatives of
15 hyaluronic acid, poly(ethylene oxide-co-propylene oxide), phosphoryl choline, polyaspirin, and poly(ester amides).

 8. The medical article of Claim 7, wherein poly(ester amides) include polymers having at least one ester bond and at least one amide bond.

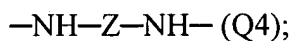
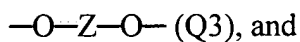
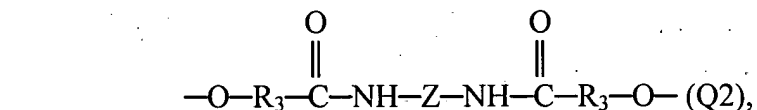
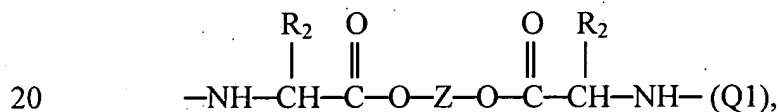
 9. The medical article of Claim 7, wherein poly(ester amides) include polymers
20 having a general formula $-[M-P]_m-[M-Q]_n-$, wherein M is a moiety represented by the structure



P is a moiety selected from a group (P1)-(P4) consisting of:



Q is a moiety selected from a group (Q1)-(Q4) consisting of:



30 wherein:

R₁ is selected from a group consisting of a straight chained or branched aliphatic alkylene group C_rH_{2r}, wherein r is an integer having the value between 2 and 12, and an aromatic group;

R₂ is selected from a group consisting of hydrogen, methyl, *iso*-propyl, *sec*-butyl, *iso*-butyl, and benzyl;

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R_3 is selected from a group consisting of methylene, methylenemethylene, *n*-propylene, *iso*-propylene, ethylenemethylene, straight chained or branched butylene, and *n*-amylene;

X is a straight chained or branched aliphatic alkylene group C_xH_{2x} , wherein x is an integer between 2 and 12;

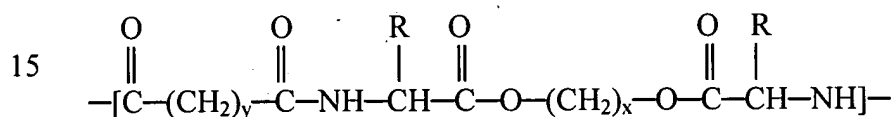
5 Y is a straight chained or branched aliphatic alkylene group C_yH_{2y} , wherein y is 2, 4, or 5;

Z is a biologically beneficial moiety derived from PEG, poly(propylene glycol), hyaluronic acid or derivatives thereof, poly(2-hydroxyethyl methacrylate) or celluloses; and

m and n are integers.

10 10. The medical article of Claim 7, wherein poly(ester amide) is a product of reaction between a diol-diamine and a dicarboxylic acid.

11. The medical article of Claim 7, wherein poly(ester amide) is a polymer that includes a unit having the formula



wherein R is selected from a group consisting of hydrogen; methyl, *iso*-propyl, *sec*-butyl, *iso*-butyl, and benzyl; x is an integer having a value between 2 and 12; and y is an integer having a value between 1 and 12.

20 12. The medical article of Claim 1, wherein the biologically beneficial polymer is a polymeric adduct comprising a biologically active agent.

13. The medical article of Claim 12, wherein the biologically active agent comprises peptides, antisense agents, rapamycin and structural derivatives or functional analogs thereof, and molecules that are sources of nitrogen oxide.

14. A method for fabricating a medical article, comprising:

5 (a) depositing a fluorinated polymer on at least a portion of an implantable medical device to form a first polymeric layer; and

(b) depositing a biologically beneficial polymer on at least a portion of the first polymeric layer to form a second polymeric layer.

15. The method of Claim 14, wherein the implantable medical device is a stent.

10 16. The method of Claim 14, wherein the fluorinated polymer includes:

(a) products of polymerization of fluorinated olefins or mixtures thereof;

(b) products of polymerization of fluorinated cyclic esters;

(c) fluorine-containing cyclic polymers having a main chain with an asymmetrical cyclic structure; or

15 (d) copolymers of perfluoro-2,2-dimethyl-1,3-dioxole with perfluoroolefins or with perfluoro(alkyl vinyl) ethers.

17. The method of Claim 16, wherein the products of polymerization of fluorinated olefins are selected from a group consisting of poly(vinylidene fluoride-co-hexafluoropropene), poly(tetrafluoroethylene), fluorinated poly(ethylene-co-propylene),
20 poly(hexafluoropropene), poly(chlorotrifluoroethylene), poly(vinylidene fluoride), poly(vinylidene fluoride-co-tetrafluoroethylene), poly(tetrafluoroethylene-co-

hexafluoropropene), poly(tetrafluoroethylene-co-vinyl alcohol), poly(tetrafluoroethylene-co-vinyl acetate), poly(tetrafluoroethylene-co-propene), poly(hexafluoropropene-co-vinyl alcohol), poly(ethylene-co-tetrafluoroethylene), poly(ethylene-co-hexafluoropropene), and poly(vinylidene fluoride-co-chlorotrifluoroethylene).

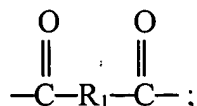
5 18. The method of Claim 16, wherein the products of polymerization of fluorinated cyclic esters is poly(perhalo-2,2-dimethyl-1,3-dioxole-co-perfluoro-2-methylene-methyl-1,3-dioxolane).

 19. The method of Claim 16, wherein the fluorine-containing cyclic polymers are selected from a group of polymers with repeating units of cyclically polymerized perfluorallyl
10 vinyl ether and/or perfluorobutenyl vinyl ether.

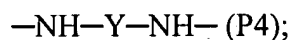
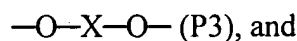
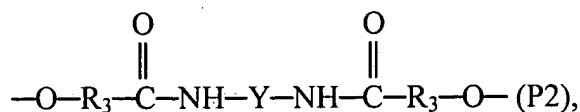
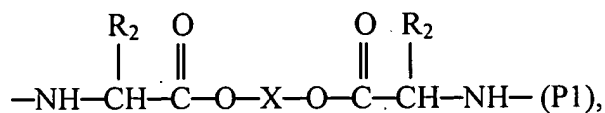
 20. The method of Claim 14, wherein the biologically beneficial polymer is selected from a group consisting of poly(ethylene-glycol), poly(ethylene-glycol)-block-poly(butylene-terephthalate)-block-poly(ethylene-glycol), poly(butylene-terephthalate)-block-poly(ethylene-glycol)-block poly(butylene-terephthalate), hyaluronic acid, derivatives of
15 hyaluronic acid, poly(ethylene oxide-co-propylene oxide), phosphoryl choline, polyaspirin, and poly(ester amides).

 21. The method of Claim 20, wherein poly(ester amides) include polymers having both at least one ester bond and at least one amide bond.

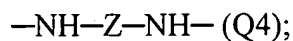
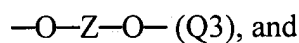
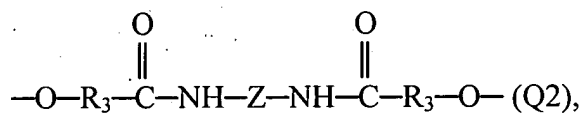
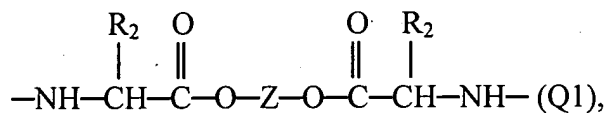
 22. The method of Claim 20, wherein poly(ester amides) include polymers having
20 a general formula $-[M-P]_m-[M-Q]_n-$, herein M is a moiety represented by the structure



P is a moiety selected from a group (P1) -- (P4), consisting of:



Q is a moiety selected from a group (Q1) -- (Q4), consisting of:



wherein:

R₁ is selected from a group consisting of a straight chained or branched aliphatic alkylene group C_rH_{2r}, wherein r is an integer having the value between 2 and 12, and an aromatic group;

R₂ is selected from a group consisting of hydrogen, methyl, *iso*-propyl, *sec*-butyl, *iso*-butyl, and benzyl;

R₃ is selected from a group consisting of methylene, methylenemethylene, *n*-propylene, *iso*-propylene, ethylenemethylene, straight chained or branched butylene, and *n*-amylene;

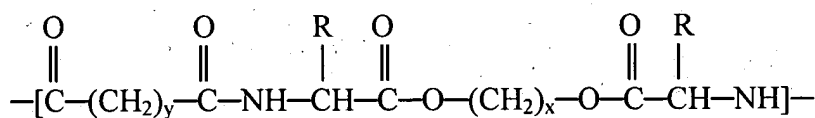
X is a straight chained or branched aliphatic alkylene group C_xH_{2x} , wherein x is an integer between 2 and 12;

Y is a straight chained or branched aliphatic alkylene group C_yH_{2y} , wherein y is 2, 4, or 5;

- 5 Z is a biologically beneficial moiety derived from PEG, poly(propylene glycol), hyaluronic acid or derivatives thereof, poly(2-hydroxyethyl methacrylate) or celluloses; and m and n are integers.

23. The method of Claim 20, wherein poly(ester amide) is a product of reaction between a diol-diamine and a dicarboxylic acid.

- 10 24. The method of Claim 20, wherein poly(ester amide) is a polymer including a unit having the formula



- 15 wherein R is selected from a group consisting of hydrogen; methyl, *iso*-propyl, *sec*-butyl, *iso*-butyl, and benzyl; x is an integer having a value between 2 and 12; and y is an integer having a value between 1 and 12.

25. The method of Claim 14, additionally including conjugating a biologically active agent to the biologically beneficial polymer.

- 20 26. The method of Claim 25, wherein the biologically active agent comprises peptides, antisense agents, rapamycin and structural derivatives or functional analogs thereof, and molecules that are sources of nitrogen oxide.